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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,883	02/05/2004	Craig Gerbi	514362001300	7413

7590 09/11/2006

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EXAMINER	
ADAMS, AMANDA S	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,883	GERBI ET AL.	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-29 and 33-39* is/are rejected.

7)☐ Claim(s) *15 and 30-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39, drawn to a system, classified in class 606, subclass 150.

II. Claims 40-52, drawn to a method, classified in class 606, subclass 139.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of Group II can be performed with tools other than those in the system of Group I. Tissue within a hollow body organ can be acquired by a pair of forceps and affixed by a laparascopic stapler, thus eliminating the need for a tissue acquisition device with an elongated tube and lumen.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Applicant's election without traverse of claims 1-39 in the reply filed on August 21, 2006, is acknowledged.

Information Disclosure Statement

6. The cover letter for the IDS dated February 5, 2004, was received on February 18, 2005, but the actual listing of the references was not received.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 3 recites the limitation "the at least two opposing members" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4, 11, 13,14,16, 17,21-23, 25- 29, 33, 34, 36, 37, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Gannoe et al (US 2004/0006351).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

11. Regarding claims 1-4, Gannoe et al disclose the invention substantially as claimed including a tissue acquisition device (fig. 13 [120]) with an elongate main body and lumen, a tissue adhering member (fig. 10 [810]), and a tissue tensioning member (fig. 10 [840]), and a tissue fixation device that can be advanced through the main lumen of the acquisition device (fig. 13 [123]), wherein the tissue adhering member and tensioning member are in apposition to one another (fig. 10), and are also longitudinally positioned relatively to one another at the distal end of the main lumen so that the tissue fixation device is stabilized from lateral movement between opposing members, and the tissue tensioning member can configure the acquired tissue into at least one fold of tissue (fig. 10 [T]).

12. Regarding claim 11, Gannoe et al disclose that the tissue adhering member and tissue tensioning member are each individually articulable from a first delivery configuration to a second expanded configuration (compare fig. 12 and fig. 12A).

13. Regarding claims 13 and 14, Gannoe et al disclose the device wherein the tissue adhering member defines at least one opening adapted to adhere tissue thereto via a

vacuum, and there is at least one vacuum tubing along the main body (fig. 13 [132] – vacuum ports).

14. Regarding claims 16 and 17, Gannoe et al disclose a first hinge member and a second hinge member each pivotally connecting a corresponding tissue adhering and tissue tensioning member to the main body, and at least one hinge member is angled relative to its corresponding member (fig. 12C [130] and [131] and par. 45).

15. Regarding claims 21-23 and 25-27, Gannoe et al disclose the elongate body of the tissue acquisition device to be flexible, and thus capable of being curved, either actively or passively, and is capable of being passively curved by having a stylet removably inserted within the main body (par. 44; and a stylet is capable of being inserted within the lumen of the main body but the stylet itself is not positively recited). This flexibility also means that the elongate main body also defines at least one bending region, and can be unidirectionally curved or curved in a plurality of directions.

16. Regarding claims 28 and 29, Gannoe et al disclose a handle (fig. 12 [122]) connected to the proximal end of the main body wherein at least one actuation mechanism ([127]) is adapted to articulate the distal end of the tissue acquisition device (par. 45).

17. Regarding claims 33, 34, 36 and 37, Gannoe et al disclose that the tissue fixation device comprises a handle connected to a cartridge assembly via a flexible shaft wherein the handle is adapted to articulate the cartridge assembly from a clamped configuration to an open configuration by rotating the stapler housing about a pivot

relative to the anvil, and the cartridge assembly comprises a stapler housing and an anvil in opposition to the stapler housing (par. 15 and 53; fig. 15, fig. 15A),

18. Regarding claim 39, Gannoe et al disclose that the tissue fixation device is adapted to maintain a fixed orientation relative to the main lumen (fig. 13).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al (US 2004/0006351).

21. Regarding claims 5-7, Gannoe et al disclose the invention substantially as claimed above further disclosing the tissue fixation device to comprise a stapler cartridge connected to the flexible shaft of the tissue fixation device (par. 53) and at least one indicator thereon on the tissue acquisition device for corresponding alignment with the tissue fixation device, the alignment of the indicator being indicative of the tissue fixation assembly being actuatable (par. 57). Gannoe et al do not disclose at least one indicator on the tissue fixation device. However, due to lack of criticality in the specification, the at least one indicator located on the shaft of the tissue fixation device was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to at least one indicator located on the tissue acquisition

device. Therefore, it would have been obvious to place the indicator on the tissue fixation device because it is capable of indicating the location of the fixation device and acquisition device relative to each other just as well as if the indicator is located on the tissue acquisition device.

22. Claims 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al (US 2004/0006351) in view of Rothfuss et al (US4,610,383).

23. Regarding claims 35 and 38, Gannoe et al disclose the invention substantially as claimed above but fail to disclose a plurality of staples. However, Rothfuss et al teach a similar tissue fixation device that has a plurality of staples within the staple housing (col. 4, lines 40-46). Having a plurality of staples within the staple housing allows multiple staples to be fired without having to reload the device, and prevents the device from the need to be repositioned after each staple has been issued. Therefore, it would have been obvious to have a plurality of staples within the tissue fixation device.

24. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al (US 2004/0006351) in view of Sugarbaker et al (US 5,928,264).

25. Gannoe et al disclose the invention substantially as claimed above but fail to disclose the actuator that corresponds to each of the tissue adhering member and tissue tensioning member being a rod that are each slidabley positionable through tubing, wherein the distal ends of the tubing are adapted to terminate proximally of a distal end of the actuation rod, wherein each actuation rod tubing is attached near or at a distal end of the main body. However, Sugarbaker et al teach actuators that correspond to each of the tissue adhering member and tissue tensioning member being

a rod that are each slidabley positionable through tubing, wherein the distal ends of the tubing are adapted to terminate proximally of a distal end of the actuation rod, wherein each actuation rod tubing is attached near or at a distal end of the main body (fig. 1, [20] and [22]). Rod shaped actuators are a well-known design in surgical tools because they provide a stable method of actuation, and tubing protects the tissue from the movement of the actuator rods. Therefore it would have been obvious to have actuators in a rod shape and have them in their respective tubing.

26. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al (US 2004/0006351) in view of Laufer et al (US 2002/0040226).

27. Gannoe et al disclose the invention substantially as claimed above except for failing to disclose a guidewire and a tapered, atraumatic distal end of the tissue acquisition device. However, Laufer et al teach that it is old and well-known in the art to use a guidewire for insertion of a tubular medical device (par. 151, figure 36B) and that a it is also well-known to use an atraumatic tip, with a tapered tip being a common shape of an atraumatic tip (par. 151, figure 36B). These designs improve the surgeon's ability to insert the device without causing harm to the surrounding location. Therefore it would have been obvious to use a guidewire and a tapered tip on the distal end of the tissue acquisition device.

Allowable Subject Matter

1. Claims 15 and 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. None of the cited references disclose or fairly suggest the limitations of claims 15 and 30-32, in particular the limitations that there is at least one meshed basket positioned within the tissue adhering member, a gasket located on the handle, and the main body comprising a plurality of adjacent links adapted to pivot through which the main lumen is defined.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

asa ASA 8/31/06

GLENN K. DAWSON
PRIMARY EXAMINER